UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

GULF MED PHARMACY, INC.,

Petitioner,

v. Case No: 2:20-cv-420-FtM-29NPM

UTTAM DHILLON, in his official capacity as Acting Administrator and UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

OPINION AND ORDER

This matter comes before the Court on plaintiff's Petition to Dissolve Immediate Suspension Order (Doc. #1) filed on April 14, 2020. The government filed a Response in Opposition (Doc. #6) on June 15, 2020. For the reasons set forth below, the Petition is denied.

I. Introduction

Plaintiff Gulf Med Pharmacy, Inc. (Gulf Med or the pharmacy) seeks to dissolve the *ex parte* suspension of its DEA Certification of Registration No. FG6290061 (COR). Plaintiff's COR was suspended by the Drug Enforcement Agency (DEA) through an Immediate Suspension Order (ISO) based on the administrative finding that plaintiff's continued registration to dispense controlled substances constituted an "imminent danger to the public health or

safety" within the meaning of 21 U.S.C. §§ 824(d) and 882. Plaintiff requests that the ISO be immediately dissolved while the ongoing DEA administrative proceeding to determine whether a permanent revocation of the COR is appropriate continues.

II. Factual Summary

Gulf Med is a family-owned business in Cape Coral, Florida which mostly serves patients and customers within a 10-mile radius of its pharmacy. Gulf Med employs Ricard Fertil, R. Ph., a pharmacist licensed since 2003, and one part-time pharmacy technician. The immediate suspension of the pharmacy's registration has resulted in the loss of all insurance-based business, the cancellation of plaintiff's primary wholesale supplier contract, and the loss of its compounding business. As a result, plaintiff now accepts cash-paying customers.

On February 9, 2018, an Application for Administrative Inspection Warrant (Doc. #6-2) was filed in the Fort Myers Division of the United States District Court for the Middle District of Florida "because the pharmacy has dispensed a high percentage of the two of the most highly abused Schedule 2 controlled substances and has not previously been subject to inspection by the DEA." (Doc. #6-2, p. 4.) An Affidavit for Administrative Inspection Warrant (Doc. #6-2, p. 5) (the Affidavit) was submitted by Margorie C. Milan, a Diversion Investigator of the DEA, assigned to the DEA, Miami Field Division. The Affidavit asserts that a review

of the Automated Reports and Consolidated Orders System (ARCOS) records for 2017 revealed that plaintiff dispensed a high percentage of highly abused controlled substances. In 2017, 1,385 prescriptions were dispensed at the pharmacy, of which 232 were for oxycodone and 117 were for hydrocodone. This represented 29% and 14% of all prescriptions, respectively. The Affidavit submits that the 43% of prescriptions for highly abused controlled substances establishes a valid public interest in establishing a full and complete accountability. The Affidavit was sworn to before a United States Magistrate Judge on February 12, 2018, and the Warrant for Inspection (Doc. #6-2, p. 13) was issued on the same day. The Return of Warrant (Doc. #6-3) indicates service of the warrant on Mr. Fertil on February 14, 2018. On the same day, a Subpoena (Doc. #6-4) was issued for the full profiles and prescription history for 28 specific patients.

Patient profiles are the documents in which a pharmacy would ordinarily record any “red flags” for a given prescription and how the pharmacy resolved the “red flags,” as required under Florida law. None of the patient profiles contained any record of notes, comments, or indication of a resolution of a “red flags”. Another Subpoena (Doc. #6-5) was issued on May 1, 2019, for the full profiles of 7 of the 28 and for an additional 7 patients. No evidence of an effort to address potential “red flag” prescriptions was found. On August 9, 2019, another Subpoena (Doc. #6-6) was

issued for the updated profile of 1 patient, and for 5 additional patients. No evidence of an effort to address potential "red flag" prescriptions was found in the documents produced pursuant to this third request. In or around September 2019, plaintiff's COR was renewed. (Doc. #1, p. 19.)

On November 18, 2019, an Order to Show Cause and Immediate Suspension of Registration (Doc. #6-1) was issued by the DEA. The Order sets forth several areas of concern that were identified. As to cocktail medications (i.e., combinations of controlled substances widely known to be abused or diverted), examples with unresolved "red flags" included:

> a. On at least three occasions between May 22, 2019, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician R.D. for Patient A.B. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 15 mg, and 30 units of diazepam 10 mg.
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> b. On at least four occasions between February 9, 2018, and July 17, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient B.Di. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 30 mg, and 60-90 units of alprazolam 1 mg.
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> c. On at least five occasions between December 28, 2018, and August 8, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician A.N. for Patient J.B. for 120 units of oxycodone 30 mg, 60 units of morphine sulfate extended release 30 mg, and 90 units of alprazolam 1 mg.
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> d. On at least four occasions between May 14, 2019, and August 6, 2019, Gulf Med Pharmacy

> filled prescriptions written on the same day by Physician M.L. for Patient R.R. for 120 units of hydromorphone 8 mg, 60 units of morphine sulfate extended release 60 mg, and 30 units of alprazolam 2 mg.
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> e. On at least four occasions between May 8, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions written on the same day by Physician M.L. for Patient B.Da. for 120 units of hydromorphone 8 mg, 30 units of morphine sulfate extended release 30 mg, and 30 units of alprazolam 2 mg. On February 12, 2018, Gulf Med Pharmacy also filled prescriptions written on the same day by another physician in the same practice—Physician D.P.—for Patient B.Da. for 150 units of hydromorphone 8 mg, 90 units of methadone 10 mg, and 30 units of alprazolam 2 mg.

(Doc. #6-1, ¶ 7.) The DEA expert opined that the cocktail of an opioid, a benzodiazepine, and carisoprodol (the "Trinity cocktail) is a serious red flag because the combination is highly dangerous. Plaintiff was found to have repeatedly dispensed Trinity cocktails without any indication that the pharmacists addressed or resolved the risk. (Id., ¶ 8.)

Additionally, from at least March 22, 2017, until at least August 8, 2019, plaintiff repeatedly filled prescriptions for patients receiving a much greater daily morphine milligram equivalent dosage of short-acting opioids than long-acting opioids. In the DEA expert's view, because these prescriptions were illogical from a pharmacological perspective, they therefore raised a red flag, yet the pharmacist failed to address it. Examples of such improper prescriptions included:

a. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient A.B. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 15 mg (equal to 30 mg of morphine per day).

b. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for Patient B.Di. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

c. On at least 18 occasions between January 10, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for Patient S.K. for 110 units of immediate release hydromorphone 8 mg (equal to 125-128 mg of morphine per day), but only 60 units of morphine sulfate extended release 15 mg (equal to 30 mg of morphine per day).

d. On at least 27 occasions between March 22, 2017, and August 8, 2019, Gulf Med Pharmacy filled prescriptions for Patient J.B. for 108-120 units of immediate release oxycodone 30 mg (equal to 162-180 mg of morphine per day), but only 60 units of morphine sulfate extended release 30 mg (equal to 60 mg of morphine per day).

e. On at least eight occasions between October 2, 2018, and August 6, 2019, Gulf Med Pharmacy filled prescriptions for Patient R.R. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 28 units of morphine sulfate extended release 60 mg (equal to 60 mg of morphine per day).

f. On at least eight occasions between January 16, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for Patient

> B.Da. for 120 units of immediate release hydromorphone 8 mg (equal to 128 mg of morphine per day), but only 30 units of morphine sulfate extended release 30 mg (equal to 30 mg of morphine per day).

(Id., ¶ 10.)

Gulf Med also regularly filled controlled substance prescriptions for individuals who traveled an unusual distance to obtain their prescriptions, which is another indication of diversion and/or abuse that should have raised a red flag. Examples included:

> a. On at least 20 occasions between November 8, 2017, and July 17, 2017, Patient A.B. traveled 45 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 15 mg, and diazepam 10 mg, which Gulf Med Pharmacy filled.
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> b. On at least five occasions between October 25, 2017, and February 12, 2018, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg and methadone 10 mg, which Gulf Med Pharmacy filled. On two of those trips—January 15, 2018, and February 12, 2018—Patient B.Da. also obtained prescriptions for alprazolam 2 mg, which Gulf Med Pharmacy also filled. Subsequently, on at least seven occasions between February 13, 2019, and August 5, 2019, Patient B.Da. traveled over 48 miles round trip to obtain prescriptions for hydromorphone 8 mg, morphine sulfate extended release 30 mg, and alprazolam 2 mg, which Gulf Med Pharmacy also filled.
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> c. On at least 17 occasions between January 17, 2018, and May 8, 2019, Patient R.D. traveled over 41 miles round trip to obtain prescriptions for hydromorphone 8 mg and lorazepam 2 mg, which Gulf Med Pharmacy filled.

(Id., ¶ 11.)

Other common red flags are the use of cash payments instead of insurance payments, or price gouging or charging more than the market rate for prescriptions for a controlled substance. (Id., ¶¶ 12-13.) From March 22, 2017, until at least August 6, 2019, Gulf Med Pharmacy repeatedly filled prescriptions for oxycodone 30 mg and hydromorphone 8 mg for patients who paid for these prescriptions in cash at substantially inflated prices that far exceeded what other area pharmacies charged. The DEA expert found that the price of 120 to 140 units of oxycodone 30 mg varied from about $1.59 to $1.63 per unit, and the sale price of 120 to 140 units of hydromorphone 8 mg varied from about $1.25 to $1.27 per unit. Examples of sales that should have raised red flags included:

> a. On at least 15 separate occasions between March 14, 2018, and April 10, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient R.D. On each occasion, Patient R.D. paid for the prescription in cash, and on all but one occasion Patient R.D. paid $4 per unit ($480 in total)—over three times the market rate.
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> b. On at least six separate occasions between February 26, 2018, and April 22, 2019, Gulf Med Pharmacy filled prescriptions for 84 to 120 units of oxycodone 30 mg for Patient T.G. On each occasion, Patient T.G. paid for the prescription in cash at a price of $4 per unit ($336 to $480 in total)—over three times the market rate.

c. On at least 16 separate occasions between March 7, 2018, and May 1, 2019, Gulf Med Pharmacy filled prescriptions for 108 to 110 units of hydromorphone 8 mg for Patient S.K. On each occasion, Patient S.K. paid for the prescription in cash at a price ranging from $3.56 per unit to $4 per unit ($392 to $432 in total)-in each case at least two-and-a-half times the market rate, and as high as over three times the market rate.

d. On at least 14 separate occasions between March 20, 2018, and April 15, 2019, Gulf Med Pharmacy filled prescriptions for 90 to 120 units of oxycodone 30 mg for Patient L.V. On each occasion, Patient L.V. paid for the prescription in cash at a price ranging from $2.50 per unit to $3.33 per unit ($300 in total)-in each case at least one-and-a-half times the market rate, and as high as twice the market rate. Further, Patient L.V. used insurance to pay for other prescriptions, including prescriptions for controlled substances such as alprazolam and zolpidem.

e. On at least 19 separate occasions between March 22, 2017, and September 7, 2018, Gulf Med Pharmacy filled prescriptions for 108 to 120 units of oxycodone 30 mg for Patient J.B. On each occasion, Patient J.B. paid for the prescription in cash at a price of $3.40 to $4 per unit ($408 to $480 in total)-in each case over twice the market rate.

f. On at least 23 occasions between November 8, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient A.B. On each occasion, Patient A.B. paid for the prescription in cash at a price of $3.73 to $4 per unit ($448 to $480 in total)-in each case over two-and-a-half times the market rate, and as high as three times the market rate.

g. On at least five occasions between October 25, 2017, and February 12, 2018, Gulf Med Pharmacy filled prescriptions for 150 units of hydromorphone 8 mg for Patient B.Da.

> Subsequently, on at least six occasions between March 13, 2019, and August 5, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Da. On each of these 11 occasions, Patient B.Da. paid for the prescription in cash at a price of $4 per unit ($480 to $600 in total)-over three times the market rate.
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> h. On at least 28 occasions between April 21, 2017, and July 17, 2019, Gulf Med Pharmacy filled prescriptions for 120 units of hydromorphone 8 mg for Patient B.Di. On each occasion, Patient B.Di. paid for the prescription in cash at a price of $4 per unit ($480 in total) over three times the market rate.
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> i. On at least 18 occasions between December 5, 2017, and least August 6, 2019, Gulf Med Pharmacy filled prescriptions for 120 to 168 units of hydromorphone 8 mg for Patient R.R. On each occasion, Patient R.R. paid for the prescription in cash at a price ranging from $4 per unit to $4.60 per unit ($480 to $672 in total)-in each case over three times the market rate.

(Id., ¶ 14.)

Based on these facts, a preliminary finding was made that plaintiff's continued registration while administrative proceedings were pending constituted "an imminent danger to the public health or safety." Therefore, registration was suspended immediately until a final determination could be made. Plaintiff now seeks to have this suspension dissolved.

III. Statutory Authority

A registration "to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or

revoked by the Attorney General" if the registrant commits acts that would make the registration "inconsistent with the public interest". 21 U.S.C. § 824(a)(4). Additionally, the registration may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard set forth in 21 U.S.C. § 823(g)(1). Id.

Under some circumstances, a registration may be suspended at the beginning of the administrative proceedings. "The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." 21 U.S.C. § 824(d)(1). The term "imminent danger to the public health or safety" means "that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." 21 U.S.C. § 824(d)(2). A federal district court has jurisdiction to dissolve the suspension of a registration. 21 U.S.C. § 824(d)(1). "The plain language of this section means that one faced with becoming the victim of the harsh expedient of suspension without prior notice may resort to the appropriate district court in search

of appropriate relief." Norman Bridge Drug Co. v. Banner, 529 F.2d 822, 823–24 (5th Cir. 1976).[1]

IV. Standard of Review

While neither party disputes the jurisdiction of a federal district court to dissolve an ISO, the parties disagree on the standard of review to be applied in such a dissolution proceeding. Plaintiff relies almost entirely on Oak Hill Hometown Pharmacy v. Dhillon, 418 F. Supp. 3d 124, 129 n.1 (S.D.W. Va. 2019), in which the district court applied a *de novo* review of the administrative record to find that the DEA failed to show a factual basis for suspension. Plaintiff argues that the record in this case is similarly insufficient to support the suspension.

The government, on the other hand, asserts that a request to dissolve an ISO must be made pursuant to a complaint and motion for temporary restraining order or preliminary injunction. "Every Middle District [of Florida] decision addressing a § 824(d) challenge did so on a motion for temporary restraining order ("TRO") or preliminary injunction." Aarric, Inc. v. Dhillon, No. 2:20-CV-306-FTM-38MRM, 2020 WL 2114600, at *1 (M.D. Fla. May 4, 2020) (collecting cases). The government argues that plaintiff has failed to comply with both the procedural and substantive

[1] In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc) the Eleventh Circuit adopted as binding precedent all the decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

requirements necessary to obtain a temporary restraining order or a preliminary injunction.

The Eleventh Circuit has held that the factual basis for an IOS is reviewed under a clearly erroneous standard. Norman Bridge Drug Co., 529 F.2d at 828–29. Additionally, since such a suspension of registration may be invoked only to avoid imminent danger to the public health and safety, the Court overlooked the failure to comply with the procedural niceties for a temporary restraining order. Norman Bridge Drug Co., 529 F.2d at 828–29. Additionally, the Eleventh Circuit has held that its review of the final decision of the DEA revoking a pharmacist's registration "may set aside the Acting Administrator's final decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. 5 U.S.C. § 706(2)(A)." Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin., 881 F.3d 823, 829 (11th Cir. 2018). As the Supreme Court has recently stated, "[u]nder this 'narrow standard of review, . . . a court is not to substitute its judgment for that of the agency, but instead to assess only whether the decision was 'based on a consideration of the relevant factors and whether there has been a clear error of judgment'". Dep't of Homeland Sec. Regents of the Univ. of California Wolf v. Vidal, 18-587, 2020 WL 3271746, at *7 (U.S. June 18, 2020)(citations omitted).

V. Application to Administrative Record

Under the pertinent statute, the DEA must demonstrate a link between a registrant's alleged transgressions and an impending death, serious bodily harm, or abuse, and must show the likelihood of those evils, based on the purported transgressions, is substantial. The Court finds that the record establishes that the factual basis for the IOS was not clearly erroneous.

The DEA clearly articulated several categories where effective controls against diversion were not in place and "red flags" were not recognized or resolved. Specifically, for cocktail medications that were dispensed, improper dosing for pain management regarding short-acting and long-acting opioids, the long distances travelled by patients seeking controlled substance prescriptions, and the cash payments at well above market rates for controlled substances. The potential harm to the public, and the public interest in this case, clearly outweigh any harm to plaintiff pending a final resolution by the DEA.

Plaintiff argues that no law provides a maximum distance that a patient may travel to obtain a prescription without being flagged as suspicious. Gulf Med argues that it has no way of knowing "how far, in DEA's opinion, is too far for a patient to travel, because there is no published standard." (Doc. #1, p. 15.) Gulf Med also argues that the Google Maps estimates do not prove that the patients actually travelled between 41 and 48 miles roundtrip.

(Id.) The government rejects this argument as driving far is a "major red flag to any pharmacist." (Doc. #6, p. 19) (citing East Main Street, 75 Fed. Reg. 66149, 66164 (DEA 2010). "All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner." 21 C.F.R. § 1306.05(a). Whether the patient travelled or not, an address located closer to other pharmacies should have been an obvious red flag. The Court rejects Gulf Med's position on this issue.

Plaintiff argues that the DEA is asking it to essentially overrule the clinical determinations of physicians by refusing to fill prescriptions calling for more short-acting opioids. Plaintiff also argues that the cash paying customers were only a small portion of the controlled substance prescriptions, and that the allegations of price gouging are not based on complete information. These arguments are also rejected. "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but **a corresponding responsibility rests with the pharmacist who fills the**

prescription." 21 C.F.R. § 1306.04(a) (emphasis added). As to the argument of the portion of cash paying customers, there is nothing clearly erroneous with the finding that it poses a red flag requiring further review.

Plaintiff argues that no specific patients were identified as having suffered harm or injury from the cocktail medications. "Plaintiff is misguided. Whether or not anyone was actually harmed is not the standard for finding imminent harm. Courts have found when infractions "demonstrate a pattern and practice of conduct which [the] DEA could reasonably conclude was inconsistent with public health and safety," an ISO is not arbitrary and capricious." George Pharmacy Inc. v. Barr, No. 6:19-CV-1480-ORL-41GJK, 2019 WL 7423550, at *4 (M.D. Fla. Sept. 23, 2019).

Even under the other suggested standards, plaintiff cannot justify dissolution of the ISO. Plaintiff has not demonstrated that the temporary suspension satisfied the standards for obtaining a temporary restraining order against its enforcement. Additionally, even if the Court were to apply a *de novo* review, the Court finds that the DEA has satisfied its burden for the issuance of the ISO. The Petition will be denied.

Accordingly, it is hereby

ORDERED:

Plaintiff's Petition to Dissolve Immediate Suspension Order (Doc. #1) is **DENIED.** The Clerk shall terminate all deadlines and close the file.

DONE and ORDERED at Fort Myers, Florida, this 23rd day of June, 2020.

JOHN E. STEELE
SENIOR UNITED STATES DISTRICT JUDGE

Copies:
Counsel of Record